

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

LISTING OF CLAIMS:

Claims 1-22 (Canceled)

Claim 23 (New): A process for solubilizing a drug substance with low water solubility, comprising mixing:

- a) a first composition which is contained in a first container prior to mixing, comprising a drug substance with low water solubility, with
- b) a second composition which is contained in a second container prior to mixing, comprising a liposomal dispersion.

Claim 24 (New): The process according to claim 23, wherein said drug substance in said first container is present as an amorphous powder which is obtained by precipitation and/or lyophilization or milling, optionally with a stabilizer.

Claim 25 (New): The process according to claim 23, wherein said drug substance in said first container is present as a solution in a hydrophilic solvent.

Claim 26 (New): The process according to claim 25, wherein said hydrophilic solvent in said first container is selected from the group consisting of ethanol, 96% ethanol, absolute glycerol, propylene glycol, ethyl lactate, polyethylene glycol 300, polyethylene glycol 400,

1,3-butandiol, succinic acid diethyl ester, triethyl citrate, dibutyl sebacate, dimethyl acetamide, DMSO, glycerineformal, glycofurol (tetraglycol), isopropanol, lactic acid butyl ester, N-methylpyrrolidone, solketol, propylene carbonate, propylene glycol diacetate, tetrahydrofurfuryl alcohol, diethylene glycol mono ethyl ether, triacetin, and combinations thereof.

Claim 27 (New): The process according to claim 24, wherein the liposomal dispersion is sufficiently optically clear to allow at least 40% of light to be transmitted at a wavelength of 660 nm using a 1 cm transmission cell or cuvette.

Claim 28 (New): The process according to claim 27, wherein said liposomal dispersion in said second container comprises liposomes having an average particle size of less than 1000 nm.

Claim 29 (New): The process according to claim 28, wherein said liposomal dispersion in said second container comprises liposomes having an average particle size of less than 300 nm.

Claim 30 (New): The process according to claim 25, wherein said first composition further comprises at least one excipient or surfactant.

Claim 31 (New): The process according to claim 30, wherein the at least one excipient or surfactant is selected from the group consisting of mono- and diacyl membrane lipids, egg phosphatidylcholine, soy phosphatidylcholine, soy phosphatidylglycerol, fatty

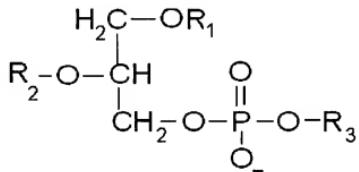
acids and salts thereof, polysorbate 80, poloxamer, polyethoxylated castor oil, and combinations thereof.

Claim 32 (New): The process according to claim 27, wherein said liposomal dispersion in said second container comprises:

a phospholipid selected from the group consisting of phosphatidylcholine, phosphatidylethanolamine, sphingomyelin, phosphatidic acid, phosphatidyl inositol, phosphatidylserine, phosphatidylglycerol, and combinations thereof, and/or

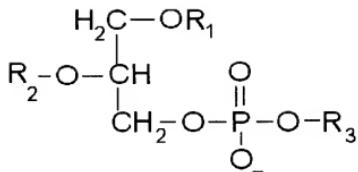
a membrane lipid selected from the group consisting of glycolipids, gangliosides, ceramides, cerebrosides, and combinations thereof.

Claim 33 (New): The process according to claim 30, wherein the phospholipid is of the formula



wherein R₁ represents C₁₀-C₂₀ acyl; R₂ represents hydrogen or C₁₀-C₂₀ acyl; R₃ represents hydrogen, 2-trimethylamino-1-ethyl, 2-amino-1-ethyl, C₁-C₄ alkyl, C₁-C₅ alkyl substituted by carboxy, C₂-C₅ alkyl substituted by carboxy and hydroxy, C₂-C₅ alkyl substituted by carboxy and amino, an inositol group or a glyceryl group or a salt thereof.

Claim 34 (New): The process according to claim 32, wherein the phospholipid is of the formula



wherein R₁ represents C₁₀-C₂₀ acyl; R₂ represents hydrogen or C₁₀-C₂₀ acyl; R₃ represents hydrogen, 2-trimethylamino-1-ethyl, 2-amino-1-ethyl, C₁-C₄ alkyl, C₁-C₅ alkyl substituted by carboxy, C₂-C₅ alkyl substituted by carboxy and hydroxy, C₂-C₅ alkyl substituted by carboxy and amino, an inositol group or a glyceryl group or a salt thereof.

Claim 35 (New): The process according to claim 23, wherein the ratio of said drug substance in said first container to the lipid in said liposomal dispersion in said second container is between 1:2 to 1:200 parts by weight.

Claim 36 (New): A kit for solubilizing a drug substance with low water solubility, comprising:

- a) a first container containing a first composition comprising a drug substance with low water solubility, and
- b) a second container containing a second composition comprising a liposomal dispersion;

said kit being designed for mixing of the first and second compositions in order to obtain an administration form of said drug substance suitable for parenteral, oral, pulmonary or topical application to a living organism.

Claim 37 (New): A kit for solubilizing a drug substance with low water solubility, comprising:

- a) a first container containing a first composition comprising:
 - i) a drug substance with low water solubility,
 - ii) at least one water miscible solvent and, optionally,
 - iii) at least one surfactant selected from the group consisting of phospholipids, fatty acids and salts thereof, polysorbate 80, poloxamer, polyethoxylated castor oil, and combinations thereof, and
- b) a second container containing a second composition comprising a liposomal dispersion;

said kit being designed for mixing of the first and second compositions in order to obtain an administration form of said drug substance suitable for parenteral, oral, pulmonary or topical application to a living organism.

Claim 38 (New): A kit according to claim 36, wherein the first and second compositions are aseptically filled into the first and second containers, or the first and second containers containing the first and second compositions are terminally sterilized.

Claim 39 (New): A kit according to claim 37, wherein the first and second compositions are aseptically filled in sterile vials or terminally sterilized.

Claim 40 (New): The process according to claim 25, wherein the liposomal dispersion is sufficiently optically clear to allow at least 40% of light to be transmitted at a wavelength of 660 nm using a 1 cm transmission cell or cuvette.

Claim 41 (New): The process according to claim 40, wherein said liposomal dispersion in said second container comprises liposomes having an average particle size of less than 1000 nm.

Claim 42 (New): The process according to claim 41, wherein said liposomal dispersion in said second container comprises liposomes having an average particle size of less than 300 nm.